REMARKS

Claims 1-10, 14, 15 and 17 have been amended. Claim 16 has been cancelled. New claims 18-21 have been introduced. Support for the amendments and the new claims can be found in the Specification as filed, for example, in Example 1, pages 24-29. No new matter has been introduced by these amendments. The following addresses the substance of the Office action.

Enablement

The Examiner has rejected Claims 15-17 under 35 USC §112, first paragraph, as being non-enabled. Specifically, the Examiner indicated that the claims are drawn to the treatment or prevention of cancer in general, and thus are not enabled by the Specification as filed. Claims 15 and 17 have been amended, claim 16 has been cancelled and new claims 18-21 have been introduced. The claims now are drawn to the method of inducing apoptosis in mammalian solid neoplastic cancer cells. These claims are fully enabled by the Specification as filed. Example 1 (pages 24-29) provides description of cytotoxic effects of the composition of the invention via induction of apoptosis in two human solid tumor cell lines.

Therefore, Claims 15, and 17-21 are fully enabled by the specification as filed, and their rejection under 35 USC §112, first paragraph should be withdrawn.

Definiteness

The Examiner has rejected Claim 14 under 35 USC §112, second paragraph, as being indefinite. Specifically, the Examiner stated that the method claim does not recite a single step, and the claim is in improper "use" form. Claim 14 has been amended accordingly.

Novelty

The Examiner has rejected Claims 9 and 10 under 35 USC §102(b) as being anticipated by Sih et al. (US 6,316,645).

> To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Sih et al. disclose 9cis, 11trans, 15cis-octadecatrienoic acid and 9cis, 13trans, 15cis-octadecatrienoic acid, but does not disclose a mixture thereof in a 1:1 w:w ratio. The composition of Sih et al. also contains 10,12,15- and 9,12,14-octadecatrienoic acids. Therefore, claims 9 and 10 are novel over Sih et al.

In addition, claims 9 and 10 are non-obvious with respect to Sih et al. as the latter does not lead a person skilled in the art to the claimed invention. There is a significant level of unpredictability in the art of conjugated linolenic acids. For instance, the location and degree of the conjugations as well as the combination of differently conjugated acids will result in different chemical and metabolic effects. The ability of a conjugated acid to be metabolized by an enzyme, for example, may critically depend on the location of the double bonds in the carbon chain. It was found that the composition of 9,11,15- and 9,13, 15-octadecatrienoic acids defined in claim 9 of the present application has the unpredictable effect of inducing apoptosis of mammalian solid neoplastic cells. Apoptosis is gene-programmed cell death and includes an orchestrated series of biochemical events leading to a distinctive cell morphology and death. Not all conjugated linolenic acids would be able to chemically and metabolically induce apoptosis. Undue experimentation would have been necessary in view of Sih et al. to come to the invention defined in claims 9 and 10.

It is also difficult to efficiently isolate certain compositions of conjugated linolenic acids in a selective manner. The compositions of claims 9 and 10, however, may be efficiently synthesized, which is advantageous.

In summary, Sih et al. does not disclose a composition comprising a mixture of 9,11,15- and 9,13,15-octadecatrienoic acids in a 1:1 w:w ratio, nor does it suggest that such a composition could be used to induce apoptosis of mammalian solid neoplastic cells.

Therefore, claims 9 and 10 are novel and non-obvious with respect to Sih et al. and their rejection under 35 USC §102(b) should be withdrawn.

Double patenting

The Examiner has provisionally rejected Claim 1-8 on the grounds of obviousness-type double patenting over claims 1-12 of copending USP Application No. 10/523,863.

Claim 1 of the present application includes the step of blending one or a mixture of vegetable oils "in the presence of water". The use of water in connection with the claimed

process provides unexpected advantages as it enables an efficient purification of the desired composition comprising conjugated linolenic acids. As noted on page 13, lines 12-23 of the present application, the process produces the conjugated trienoic acids with a high selectivity, in a short time period and in relatively mild conditions. Therefore, claims 1-8 are non-obvious with respect to the claims of the copending application, and their rejection should be withdrawn

The Examiner has provisionally rejected Claim 15-17 on the grounds of obviousness-type double patenting over claims 1-12 of copending US Patent Application No. 10/523,863 in view of Shirai et al. (JP 2000336029 A). .

Claim 16 has been cancelled, claims 15 and 17 have been amended and new claims 18-21 have been added to better define the method. The amended claims 15 and 17 as well as the new claims 18-21 pertain to a method of inducing apoptosis of mammalian solid neoplastic cells by contacting the cells with a therapeutically effective amount of the composition defined in claim 9, that is a composition comprising a mixture of 9,11,15- and 9,13,15-octadecatrienoic acids in a 1:1 w:w ratio. Shirai et al. neither disclose nor suggest the composition defined in claim 9 or that such a composition could be used to induce apoptosis of mammalian solid neoplastic cells. Shirai et al. do not suggest that breast cancer cells can be treated as is now claimed in claim 17. Although in Shirai et al. conjugated linolenic acids have been recognized as antitumor products, all the conjugated acids in this reference are trienes tri-conjugated, whereas the isomers disclosed and claimed in the present application are trienes di-conjugated. Moreover, Shirai et al. does not teach the use of the specific mixture of 9,11,15- and 9,13,15-octadecatrienoic acids according to the invention in the inducement of apoptosis of mammalian solid neoplastic cells.

More specifically, the applicant notes that linolenic acid compositions as well as the metabolic and therapeutic effects of various combinations of linolenic acids with different conjugations is a delicate science. As touched on above, there is a significant level of unpredictability in the art of conjugated linolenic acids and not all compositions would be able to chemically and metabolically induce apoptosis. Undue experimentation would have been necessary in view of the prior art and the copending application to arrive at the claimed invention.

It would therefore not have been obvious to a person skilled in the art to combine 9,11,15 and 9,13,15 conjugated linolenic acids to arrive at the composition defined in claim 9, to then be used to induce apoptosis of mammalian solid neoplastic cells as claimed in claims 18-21 .

Therefore, Claims 15, and 17-21 are non-obvious over the cited references, and their rejection should be withdrawn.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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AMEND

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